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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,952	06/25/2003	Peter Lyon Harris	292-PDD-99-20-CON-[70P2]	3111
79990 7590 09/16/2010 C. R. Bard, Inc. Bard Peripheral Vascular, Inc. 1415 W. 3rd Street P.O. Box 1740 Tempe, AZ 85280-1740				
EXAMINER WILLSE, DAVID H				
ART UNIT 3738		PAPER NUMBER		
NOTIFICATION DATE 09/16/2010		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

BPVIP.Docket@crbard.com
Jacki.Daspit@crbard.com

Office Action Summary

Application No.

10/603,952

Applicant(s)

HARRIS ET AL.

Examiner

David H. Willse

Art Unit

3738

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14-22, and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-22, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-11, 14, 16, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ehrenfeld, US 5,156,619, which discusses a prior art example including a generally uniform surface (column 1, line 65, to column 2, line 5) and a first nominal or minimal inner diameter (column 1, lines 51-57; Figures 1-3) that tapers to a smaller second nominal or minimal inner diameter (column 2, lines 17-20) adjacent the end formation **23** (column 2, lines 6-9). Regarding claim 2 and others, the crimps **16** impart convexity to portions of the “toe” region, and the generally circular cylindrical geometry of segment **12** (Figure 1) likewise defines a convexity. Regarding claim 7 and others, a second end formation would have been inherent from column 1, lines 5-8.

Claims 6, 15, 17, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrenfeld, US 5,156,619. Regarding claim 6, diameters within the particular ranges would

have been obvious from the ranges specified by Ehrenfeld (column 1, lines 54-57; column 4, lines 10-15) and from the diversity of blood vessel sizes known to the ordinary practitioner. Regarding claim 15 and others, PTFE would have been an obvious alternative thread or coating in view of column 1, lines 13-20.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matterson, US 4,530,113. Forming the shunt **10** of Figure 6 without the pleats or corrugations **12** (so as to create a *constant* inner dimension) would have been an obvious step backward (column 6, lines 49-59) in order to simplify manufacture. The inner arc lengths and diameters along the ends **44** are variable by virtue of the oblique cut (column 7, lines 9-11), which also defines an elongate, non-circular opening of greater area than that of a cross-section transverse to a central axis along an intermediate portion of the shunt **10**. Attention is also directed to column 6, line 32.

Claims 1-5, 7, 14, 16, 18, 19, 21, and 27 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pintauro et al., US 5,782,916. Figure 13 illustrates an end formation **114** *capable* of connection to a blood vessel opening (column 3, lines 58-64; column 4, lines 35-43; column 9, line 8 et seq.) and a first diameter portion surrounding the valve **124** and tapering to a smaller second diameter portion (column 7, lines 66-67) adjacent the end formation **114**, which defines openings having non-circular perimeters (Figures 1, 8, 10, 14, and 15; column 8, lines 5 and 14-18; column 4, lines 8-20; etc.). Regarding claim 2, a second transverse diameter may be defined near the reinforcing ring **17** or **117** (Figures 1, 8, 10, and 13), and the *internal* toe surface is concave (Figure 13). Regarding claim 21, the second engagement may be viewed as involving anchor **116**, with valve **124** defining a lesser third diameter portion.

Claims 6, 15, 17, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pintauro et al., US 5,782,916. Regarding claim 6, the particular dimensions would have been within the realm of obvious variants in view of the diversity of pertinent anatomical dimensions found in the animal kingdom and in view of column 4, lines 17-20 and 32-34; column 8, lines 3-6 and 38-44; and column 8, line 49 et seq. Regarding claim 15 and others, PTFE would have been immediately obvious from column 8, lines 45-48.

Response to Applicant's Remarks

Regarding Ehrenfeld, the prior art example includes a generally uniform surface in that the integrity of the knit or woven graft **11** is maintained by the joining of the legs **13** and **14** to the main body **12** at crotch **15** (column 1, line 65, to column 2, line 5), with “uniform” being defined, for example, as “presenting an unvaried appearance of surface, pattern, or color” (*Merriam-Webster's Collegiate Dictionary*, 10th ed.: 1996) and “generally” being a broad term. The examiner therefore disagrees with the Applicant's assertion that “the presence of crimps *necessarily* means that any tubular portion shown does not include a ‘generally uniform surface’” (Applicant's reply of July 6, 2010: sentence bridging pages 6 and 7; emphasis in original), particularly in the absence of any definition (in a manner prescribed in MPEP § 2111.01) for such a claimed term. As for the Applicant's claims 18 and 21, there is nothing in the language that requires the “first diameter portion” (e.g., claim 18, line 2) to possess *only one* diameter. In fact, the Applicant's own pertinent embodiment having the narrowed portion **70** appears to also include a tapering “first diameter portion extending along a majority of the length of the tube” (claim 18, lines 2-3; Figures 9, 11, and 13). And elongated crimped surfaces may certainly be characterized by nominal maximum and minimum diameters, for instance.

Applicant argues that the Pintauro et al. device “is not ‘configured for surgical connection to an opening formed in a blood vessel’ as recited in independent claim 1” (Applicant’s reply of July 6, 2010: page 8, lines 6-7; emphasis in original). The examiner agrees that the prosthesis is designed for controlling urinary continence (abstract, first line), but the implant is also *capable* of connection to a blood vessel opening, *even though such was not the intent*, because of the soft, resilient materials used (Pintauro et al.: column 8, lines 38-44) and because of the continuum of sizes and shapes existing in blood vessels (such as near venous valves, bifurcations, aneurysms, and so on). The Applicant replicates Figure 10 of Pintauro et al. but appears to overlook the configuration of Figure 13 clearly relied upon in the grounds of rejection. The Applicant’s own “chamber” is certainly not completely enclosed. A generally frusto-conical (but non-circular: column 8, lines 14-15, of Pintauro et al.) chamber portion exists just above the collapsed portion (Figure 13 of Pintauro et al.), the “anchor 14 can extend circumferentially up to as much as from approximately 270° to 300°” (Pintauro et al.: column 4, lines 10-11), and nothing in Applicant’s claim 1 and others requires that the opening be planar.

Matterson was certainly aware of non-crimped tubular grafts, and even though such embodiments are viewed to be inferior as to maintaining an open configuration, such variants are advantageous economically in that the crimping step and possibly the heat-setting step (Matterson: column 6, lines 46-56) are not required. The generally elliptical shape created by the oblique cut innately involves a continuum of diameters (i.e., lengths of straight lines through an elliptical center or across circular arcs), and the diminishing arc lengths near the oblique opening are themselves also within the scope of the term “dimension” (instant claim 27, line 3).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday through Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/David H. Willse/
Primary Examiner
Art Unit 3738**